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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Helmut Heide, Joachim Pabst, Albrecht Dinkelaker and
Olaf Pobantz

Serial No.: 10/085,526

Filing Date: February 26, 2002

Art Unit: Not Yet Assigned

Examiner: Not Yet Assigned

For: RESORBABLE BONE REPLACEMENT AND BONE FORMATION MATERIAL

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New York, New York 10151

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Hon. Commissioner of Patents and Trademarks Washington, DC 20231, on May 17, 2002.

Ronald R. Santucci, Reg. No. 28,988

Name of Applicant, Assignee or Registered Representative

Ronald R. Santucci
Signature
May 17, 2002

Date of Signature

Assistant Commissioner
For Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Dear Sir:

Preliminary to the examination of the above-identified patent application kindly amend the application as follows:

In the Specification:

On page 1, immediate below the title, please add the following:

Cross-Reference to Related Applications:

This application is a continuation-in-part of International Application No.

PCT/EP00/08382, filed August 28, 2000, now WO 01/13970 A1 published March 1, 2001, and claims priority benefits of German application DE 19940717.7 filed August 26, 1999.

In the Claims:

Kindly rewrite claims 1-19 as follows:

1. (Amended) Resorbable bone replacement and bone formation material (augmentation material) based on porous β -tricalcium phosphate (β -TCP), which can be produced by
 - (a) baking a phosphate powder of a chemical composition the residue on baking of which yields theoretically chemically pure tricalcium phosphate and
 - (b) providing the baked blanks with tubular pores,

wherein

β -tricalcium phosphate (β -TCP) is baked at least twice and especially at least three times and the formation of the thermodynamically stable adjacent phases of β -TCP is prevented by
 - (i) powdering the presynthesis product obtained according to step (a),
 - (ii) optionally baking the powdered presynthesis product together with phosphate powder according to step (a) and powdering the material obtained and optionally repeating step (ii) once or more than once,
 - (iii) compressing the powdered product obtained in step (i) or step (ii) together with phosphate powder according to step (a) to form blanks and subjecting the blanks formed to final ceramic baking and

(iv) subjecting the compressed or baked blanks, at least 99.5% of which consists of pure β -tricalcium phosphate (β -TCP), to step (b).

2. (Amended) Formation material according to claim 1, wherein the chemical and crystalline purity, the fabric structure, the microporosity and the macroporosity of the augmentation material make possible rapid, foreign-body-reaction-free, biochemically orientated integration and resorption in bone.

3. (Amended) Formation material according to claim 1, which can be produced by

- (i) starting from a presynthesis product obtainable by baking a phosphate powder of a chemical composition the residue on baking of which yields theoretically chemically pure tricalcium phosphate as a presynthesis product, and powdering that presynthesis product,
- (ii) optionally baking the powdered presynthesis product together with phosphate powder according to step (i) and powdering the material obtained and optionally repeating step (ii) once or more than once,
- (iii) compressing the powdered product obtained in step (i) or step (ii) together with phosphate powder according to step (i) to form blanks and subjecting the blanks formed to final ceramic baking and
- (iv) providing the compressed or baked blanks with tubular pores.

4. (Amended) Formation material according to claim 1, obtainable by baking at a temperature below 1200°C in the β -tricalcium phosphate (β -TCP) phase region.

5. (Amended) Formation material according to claim 1, obtainable by using in step (ii) and/or step (iii) from 1 to 50% by weight, especially from 1 to 25% by weight, phosphate powder (based on the total weight of phosphate powder and already baked material).

6. (Amended) Formation according to claim 1, wherein the sintered structure has a uniform, interconnected microporosity having pore widths in the region of from 2 to 15 μm and especially from 4 to 10 μm and/or the matrix of the augmentation material is tightly sintered to microporosity, especially with microparticles that are loosely bound in the sintered structure and/or phagocytosable, having a diameter of max. 15 μm , being absent.

7. (Amended) Formation material according to claim 1, wherein a microporosity of 20% by volume or more, preferably from 20 to 40% by volume, and especially 30% by volume or more, based on the overall porosity (consisting of micro- and macro-porosity).

8. (Amended) Formation material according to claim 1, obtainable by providing the compressed blank with tubular pores with the aid of a compression mould of optionally more than one part.

9. (Amended) Formation material according to claim 1, obtainable by providing the baked blank with tubular pores by means of milling or drilling.

10. (Amended) Formation material according to claim 1, wherein the formation material is in block form, with 2- or 3-dimensionally oriented macroscopic tubular pores passing through each block, which are in each case arranged perpendicular to the block surface or to an imaginary plane laid through the block or against the block and form an interconnecting system of tubular pores.

11. (Amended) Formation material according to claim 10, wherein a block intended for implantation, together with its tubular pores, can be so oriented for implantation or on processing prior to implantation that at least one direction of orientation of the tubular pores corresponds to a biomechanically or biofunctionally intended direction of growth.

12. (Amended) Formation material according to claim 1, wherein tubular pores that have radii in the region of from 100 to 2000 μm and especially from 500 to 2000 μm .

13. (Amended) Formation material according to claim 1, wherein the formation material, present in block form, is penetrated by the tubular pores spaced apart at a defined spacing with respect to one another, especially at a spacing that corresponds to a wall thickness of not more than from 1500 to 4000 μm and especially from 2000 to 3000 μm .

14. (Amended) Formation material according to claim 1, wherein an overall porosity (consisting of micro- and macro-porosity) of more than 50% by volume.

15. (Amended) Formation material according to claim 1, wherein a macroporosity of from 25 to 50% by volume, and especially from 30 to 40% by volume, based on the overall porosity (consisting of micro- and macro-porosity).

16. (Amended) Formation material according to claim 1, wherein the block form is a simple geometric shape, especially that of a cube, cuboid, taper, cone or disc.

17. (Amended) Formation material according to claim 1, wherein it is a semi-finished product, especially for subsequent mechanical processing, preferably for individual adaption in the case of bone defect in mouth or jaw medicine, orthopaedic surgery or trauma surgery.

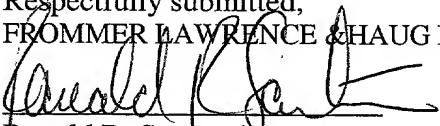
18. (Amended) Formation material according to claim 11, wherein the material is compressed, especially baked or sintered, only to a degree such that it can be processed using tools available to the practitioner, especially using a rasp, file, scalpel or a dentist's instrument.

19. (Amended) Formation according to claim 11, wherein it has been brought into the form of an individual prosthesis with the aid of a medical CAD/CAM method.

REMARKS

The claims of the above referenced application have been amended to remove all multiple dependencies. No new matter has been added. Accordingly, an early examination of the application is respectfully requested.

The Commissioner is authorized to charge any additional fees that may be required to
Deposit Account No. 50-0320.

Respectfully submitted,
FROMMER LAWRENCE & HAUG LLP
By: 
Ronald R. Santucci
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APPENDIX (version with markings):

On page 1, immediate below the title, please add the following:

--Cross-Reference to Related Applications:

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In the Claims:

Kindly rewrite claims 1-19 as follows:

1.(Amended) Resorbable bone replacement and bone formation material (augmentation

material) based on porous β -tricalcium phosphate (β -TCP), which can be produced by

(a) baking a phosphate powder of a chemical composition the residue on baking of which
yields theoretically chemically pure tricalcium phosphate and

(b) providing the baked blanks with tubular pores,

[characterized in that] wherein

β -tricalcium phosphate (β -TCP) is baked at least twice and especially at least three times and
the formation of the thermodynamically stable adjacent phases of β -TCP is prevented by

- (i) powdering the presynthesis product obtained according to step (a),
- (ii) optionally baking the powdered presynthesis product together with phosphate powder
according to step (a) and powdering the material obtained and optionally repeating
step (ii) once or more than once,
- (iii) compressing the powdered product obtained in step (i) or step (ii) together with
phosphate powder according to step (a) to form blanks and subjecting the blanks
formed to final ceramic baking and

- (iv) subjecting the compressed or baked blanks, at least 99.5% of which consists of pure β -tricalcium phosphate (β -TCP), to step (b).

2. (Amended) Formation material according to claim 1, [characterized in that] wherein the chemical and crystalline purity, the fabric structure, the microporosity and the macroporosity of the augmentation material make possible rapid, foreign-body-reaction-free, biochemically orientated integration and resorption in bone.

3. (Amended) Formation material according to [one of the preceding claims] claim 1, which can be produced by

- (i) starting from a presynthesis product obtainable by baking a phosphate powder of a chemical composition the residue on baking of which yields theoretically chemically pure tricalcium phosphate as a presynthesis product, and powdering that presynthesis product,
- (ii) optionally baking the powdered presynthesis product together with phosphate powder according to step (i) and powdering the material obtained and optionally repeating step (ii) once or more than once,
- (iii) compressing the powdered product obtained in step (i) or step (ii) together with phosphate powder according to step (i) to form blanks and subjecting the blanks formed to final ceramic baking and
- (iv) providing the compressed or baked blanks with tubular pores.

4. (Amended) Formation material according to claim 1 [or 3], obtainable by baking at a temperature below 1200°C in the β -tricalcium phosphate (β -TCP) phase region.

5. (Amended) Formation material according to [one of claims 1, 3 or 5] claim 1, obtainable by using in step (ii) and/or step (iii) from 1 to 50% by weight, especially from 1 to 25% by weight, phosphate powder (based on the total weight of phosphate powder and already baked material).

6. (Amended) Formation according to [one of the preceding claims] claim 1, [characterized in that] wherein the sintered structure has a uniform, interconnected microporosity having pore widths in the region of from 2 to 15 μm and especially from 4 to 10 μm and/or the matrix of the augmentation material is tightly sintered to microporosity, especially with microparticles that are loosely bound in the sintered structure and/or phagocytosable, having a diameter of max. 15 μm , being absent.

7. (Amended) Formation material according to [one of the preceding claims] claim 1, [characterized by] wherein a microporosity of 20% by volume or more, preferably from 20 to 40% by volume, and especially 30% by volume or more, based on the overall porosity (consisting of micro- and macro-porosity).

8. (Amended) Formation material according to [one of the preceding claims] claim 1, obtainable by providing the compressed blank with tubular pores with the aid of a compression mould of optionally more than one part.

9. (Amended) Formation material according to [one of the preceding claims] claim 1, obtainable by providing the baked blank with tubular pores by means of milling or drilling.

10. (Amended) Formation material according to [one of the preceding claims] claim 1, [characterized in that] wherein the formation material is in block form, with 2- or 3-dimensionally oriented macroscopic tubular pores passing through each block, which are in each case arranged perpendicular to the block surface or to an imaginary plane laid through the block or against the block and form an interconnecting system of tubular pores.

11. (Amended) Formation material according to claim 10, [characterized in that] wherein a block intended for implantation, together with its tubular pores, can be so oriented for implantation or on processing prior to implantation that at least one direction of orientation of the tubular pores corresponds to a biomechanically or biofunctionally intended direction of growth.

12. (Amended) Formation material according to [one of the preceding claims] claim 1, [characterized by] wherein tubular pores that have radii in the region of from 100 to 2000 μm and especially from 500 to 2000 μm .

13. (Amended) Formation material according to [one of preceding claims] claim 1, [characterized in that] wherein the formation material, present in block form, is penetrated by the tubular pores spaced apart at a defined spacing with respect to one another, especially at a spacing that corresponds to a wall thickness of not more than from 1500 to 4000 μm and especially from 2000 to 3000 μm .

14. (Amended) Formation material according to [one of preceding claims] claim 1,
[characterized by] wherein an overall porosity (consisting of micro- and macro-porosity) of
more than 50% by volume.

15. (Amended) Formation material according to [one of the preceding claims] claim 1,
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16. (Amended) Formation material according to [one of the preceding claims] claim 1,
[characterized in that] wherein the block form is a simple geometric shape, especially that of
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17. (Amended) Formation material according to [one of the preceding claims] claim 1,
[characterized in that] wherein it is a semi-finished product, especially for subsequent
mechanical processing, preferably for individual adaption in the case of bone defect in mouth
or jaw medicine, orthopaedic surgery or trauma surgery.

18. (Amended) Formation material according to [one of claims 11 to 17] claim 11,
[characterized in that] wherein the material is compressed, especially baked or sintered, only
to a degree such that it can be processed using tools available to the practitioner, especially
using a rasp, file, scalpel or a dentist's instrument.

19. (Amended) Formation according to [one of claims 11 to 17] claim 11, [characterized in that] wherein it has been brought into the form of an individual prosthesis with the aid of a medical CAD/CAM method.